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510 (K) SUMMARY – TENOLIG®

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

SUBMITTER:

Fournitures Hospitalières Industrie
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Phone number: 33.2.98.55.68.95
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AUG - 9 2006

COMPANY CONTACT:

Christine Quendez
Regulatory Affairs Manager
Phone number: 33.2.98.55.68.95
Fax number: 33.2.98.53.42.13

DATE PREPARED: Junuary 30th 2006

DEVICE NAME:

Trade Name:	TENOLIG®
Common name:	Nonabsorbable Polyester Surgical Suture
Classification name:	Non-absorbable poly(ethylene terephthalate) surgical suture 21 C.F.R. Section 888.5000

PREDICATE DEVICES:

Name	POLY-TAPES®
Manufacturer:	Xiros Plc.
510(K) number:	K002172

Name	Modified coated VICRYL®
Manufacturer:	Ethicon Inc.
510(K) number:	K022269

DEVICE DESCRIPTION :

Tenolig® consists of:

- a thread in polyester (poly(ethylene terephthalate)) with a diameter of 0.85mm and 360mm length, crimped at its proximal end, onto which is mounted a 7mm-wide harpoon, and crimped at its distal end by a triangular-tipped needle, 150mm long, slightly curved at delivery and which can be adjusted during surgery according to a curve suitable for the type of rupture treated;
- two perforated lead pellets for tightening;

- an UHMW polyethylene disc, with a convex surface offering support that does not excessively compress the skin and a flat surface.

A complete kit required for normal percutaneous tenosynthesis includes two Tenolig®.

INTENDED USE :

Tenolig is indicated for recent ruptures of the Achilles tendon.

TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICES :

TENOLIG® is a device for mini-invasive (percutaneous) Achilles tendon suture. To obtain the FDA agreement, we will compare the TENOLIG® with two predicate devices :
- The first one is "POLY-TAPES®" from Xiros, which is made with the same material (PET)
- The second one is a braided suture "Vicryl" from Ethicon, which is also used for soft tissue approximation like the Achilles tendon suture.

The mechanical characteristics of TENOLIG® and VICRYL® are compared with a tensile test. The VICRYL® diameter and the kind of suture for this test are determined following the surgical technique of "ACHILLON" from Newdeal (An Integra Lifesciences Company). Both systems have the same indication of use, it means the meeting of the two extremities of Achilles tendon lesion.

PERFORMANCE DATA:

Risk to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.
Performance testing was performed in accordance with the recommendations set up in the FDA Guidance document: « Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA ». Tensile tests were performed to characterize in tension the strength of the crimping of the braid with the needle and of the braid with the spear. All results demonstrate that the Tenolig® is safe and effective.
Biocompatibility testing were conducted according to the NF S 94167 French standard. The results correspond to the requirements of the ISO-10993 standard, which requires to conduct testing in appropriate body contact and duration.

CONCLUSION:

Even if the design of the Tenolig® and the predicate devices is different, it does not raise new question of safety and effectiveness. The claim of substantial equivalence is based on:
On the one hand :
- the intended use of the POLY-TAPES® from Xiros and TENOLIG® which are the same,
- the use of the percutaneous tenorraphy to repair Achilles tendon ruptures,
- the post-surgery period which is based on the same principles,
- the material use for the thread.

On the other hand :
- On the surgical technique of suture VICRYL® which is similar

The technological characteristic differences do not raise new question of safety and effectiveness. Performance testing, biocompatibility testing and clinical data can prove that the Tenolig® is reliable and safe.
The Tenolig® is substantially equivalent to the selected predicate device in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

Fournitures Hospitalieres Industrie
% Ms. Christine Quendez
Regulatory Affairs Manager
6 Rue Nobel, Z.I. de Kernevez
29000 Quimper, France

Re: K060367
Trade/Device Name: TENOLIG®
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: July 20, 1998
Received: July 24, 1998

Dear Ms. Quendez:

This letter corrects our substantially equivalent letter of July 9, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060367

Device Name: TENOLIG®

Indications for Use: TENOLIG® is indicated for surgical repair of Achilles tendon ruptures by percutaneous approach

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use ___X___ AND/OR Over the counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

510(k) Number K060367

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)